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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,467	01/08/2001	Kevin D. Eichelberger	DEKA:260US/MBW	7312

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EXAMINER	
FOX, DAVID T	
ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/756,467	Eichelberger
Examiner	**Group Art Unit**
FOX	1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 3/29/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-28 is/are pending in the application.

Of the above claim(s)____ is/are withdrawn from consideration.

☐ Claim(s)____ is/are allowed.

☑ Claim(s) 1-28 is/are rejected.

☐ Claim(s)____ is/are objected to.

☐ Claim(s)____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other____

Office Action Summary

The specification is objected to on page 27, lines 10 and 11, for its inclusion of blank lines. It is noted that the claims have been amended to insert the ATCC Accession Number. The specification should also be amended to insert the date of deposit and the Accession Number.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that applicants have deposited the plant but there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has

been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,

(e) the deposit will be replaced if it should ever become inviable.

Claims 9 and 22-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 26 is broadly drawn to any transgenic plant which contains any heterologous coding sequence conferring any trait. Claims 9, 25 and 27-28 are also broadly drawn to any "single locus conversion" plant comprising one or more traits introgressed into the claimed variety by backcrossing or other traditional means, including the traits of yield enhancement and enhanced yield stability. Claims 22-24 are also broadly drawn to any F1 hybrid or subsequent progeny produced by crossing the exemplified inbred line with any of a multitude of non-exemplified inbreds, or any descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners.

No guidance has been provided for the description or characterization of a multitude of heterologous coding sequences conferring a multitude of traits. No guidance has been provided regarding the identification or characterization of parental lines possessing a single gene which results in enhanced yields or enhanced yield stability. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would

disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California* v. *Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

Claims 9 and 22-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 26 is broadly drawn to any transgenic plant which contains any heterologous coding sequence conferring any trait. Claims 9, 25 and 27-28 are also broadly drawn to any "single locus conversion" plant comprising one or more traits introgressed into the claimed variety by backcrossing or other traditional means, including the traits of yield enhancement and enhanced yield stability. Claims 22-24 are also broadly drawn to any F1 hybrid or subsequent progeny produced by crossing the exemplified inbred line with any of a multitude of non-exemplified inbreds, or any descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners.

No guidance has been provided for the description or characterization of a multitude of heterologous coding sequences conferring a multitude of traits. No guidance has been provided regarding the identification or characterization of parental lines possessing a single gene which results in enhanced yields or enhanced yield stability. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with the expression of the remaining traits whose

combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny.

Hunsperger et al (1996, U.S. Patent 5,523,520), Kraft et al (2000, Theor. Appl. Genet. 101:323-326), and Eshed et al (1996, Genetics 143:1807-1817) teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (see, e.g., column 3, lines 26-46). In particular, Hunsperger et al teach that a gene conferring miniature plant stature which has been identified and genetically stabilized in one cultivar of *Petunia hybrida*, a member of the Solanaceae, does not confer a miniature phenotype when introgressed into the genome of a variety of other *Petunia hybrida* cultivars (see, e.g., column 3, lines 40-41).

Kraft et al teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype-specific and loci-dependent in nature (see, e.g., page 323). Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of

alleles at a number of different loci, and that very little is typically known about the plant breeding materials, which contributes to the unpredictability of the effect. Eshed et al teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, e.g., page 1815).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to isolate and obtain a multitude of transgenes encoding a multitude of traits, and to evaluate their expression in transformed corn. Undue experimentation would have also been required to identify a multitude of breeding partners possessing any single locus conversion trait including the typically polygenic traits of yield enhancement and enhanced yield staiblity, and to evaluate the transmission and expression of these traits in progeny of crosses with inbred 5750 and the non-5750 parent, while also evaluating and obtaining the retention of all other 5750-specific traits.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 25-28 are confusing in their characterization of inbred 5750, which possesses a particular collection of traits and genes, as simultaneously comprising additional genes conferring male sterility or other non-5750 traits.

Cancellation of claims 9 and 22-28, and submission of the following new claims would obviate the rejections above under 35 USC 112. Support for these claims can be found on pages 29-33 of the specification.

--Claim 29. A method of producing a male sterile corn plant comprising transforming the corn plant of claim 4 with a nucleic acid molecule that confers male sterility.

Claim 30. A male-sterile corn plant produced by the method of claim 29.

Claim 31. A method of producing an herbicide resistant corn plant comprising transforming the corn plant of claim 4 with a transgene that confers herbicide resistance.

Claim 32. An herbicide resistant corn plant produced by the method of claim 31.

Claim 33. A method of producing an insect resistant corn plant comprising transforming the corn plant of claim 4 with a transgene that confers insect resistance.

Claim 34. An insect resistant corn plant produced by the method of claim 33.

Claim 35. A method of producing a disease resistant corn plant comprising transforming the corn plant of claim 4 with a transgene that confers resistance to bacterial, fungal, nematode or viral disease.

Claim 36. A disease resistant corn plant produced by the method of claim 35.

Claim 37. A method of producing a corn plant with modified carbohydrate composition comprising transforming the corn plant of claim 4 with a transgene conferring waxy starch.

Claim 38. A corn plant produced by the method of claim 37.--

The claims are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an inbred corn line with the unique collection of genes and morphological traits possessed by 5750, or hybrids or single locus conversions thereof. The closest prior art, Pfund et al (U.S. 5,424,483), teaches an inbred corn plant with straight internodes, absent sheath anthocyanin, few marginal waves, green glume, absent glume band, upright ear, semi-conical ear shape, green fresh husk color, buff dry husk color, red cob, normal endosperm and yellow endosperm (see, e.g., Table 2, columns 14-15). However, the prior art corn inbred differs from the claimed inbred in its possession of dark green leaves, heavy sheath pubescence, tan anthers and silks, intermediate husk opening, curved kernel rows, Dent-type kernels, and orange side color, among other traits.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

May 10, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638